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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/996,768	12/23/1997	ALBRECHT WENDEL	P61750USO	9465

7590 12/07/2001

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/07/2001

*[Signature]*

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	08/996,768	WENDEL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 May 2001.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 19-25 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 19-25 and 27-29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on May 25, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/996,768 is acceptable and a CPA has been established. An action on the CPA follows.
  
2. Claims 19-25 and 27-29 are under consideration in this Office Action.

### ***Drawings***

3. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the examiner allows the application.

### ***Response to Arguments***

4. Applicant's arguments filed May 4, 2000 have been fully considered but they are not persuasive.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The rejection of claims 19-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons already made of record.

Applicants urge that the preamble and final steps recited in the claims are sufficient to make the claim complete. However, it is the examiner's position that the claims are incomplete. The claims state a reaction of blood will be determined, however

the final step recites a detecting and/or measuring step. The claims lack a correlation step. The correlation step should correlate detecting the immunofunctional, toxic and/or modulatory reaction and determining the reaction of blood. Clarification is required to overcome this rejection. Therefore the rejection is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The rejection of claims 19-25 and 27-29 under 35 U.S.C. 103(a) as being unpatentable over Wendel et al. (EPA 741,294, DE Appl. 19, 516,247), in view of Boyse et al., (US Patent 5,004,681) is maintained for reasons already of record.

The rejection was on the grounds that it would have been obvious at the time of applicants invention to use the frozen blood samples and cryopreservation of blood as taught by Boyse et al., in the method of determining the reaction of blood as taught by Wendel et al., because Boyse et al., teach that it would be advantageous in methods to use frozen blood which does not lose its ability to function which can be cryopreserved and stored until use.

Applicant's argue that there is no suggestion to combine the references, because Boyse et al., (5,004,681), can only be used in therapeutic methods and products, however it is the examiner's position that Boyse et al., teach inspection and testing of

Art Unit: 1645

the blood that can be used to test for the presence of bacterial cultures or diagnostic screening for pathogenic microorganisms. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, it would have been obvious to have used the frozen blood samples and cryopreservation of blood as taught by Boyse et al., (5,004,681) in the method of Wendel et al., because one having ordinary skill in the art would have been motivated to make such a change, as a mere alternative and functionally equivalent blood sample, frozen/non-frozen. Since only the expected results would have been obtained, the prior art clearly teaches the use of frozen or cryopreserved blood samples, therefore a skilled artisan would have had a reasonable expectation of success in switching the state of the samples. The use of alternative samples would have been desirable to those of ordinary skill in the art based on the benefits of using cryopreserved blood, i.e., that it would be advantageous in methods to use frozen blood that does not lose its ability to function which can be cryopreserved and stored for later use.

Therefore, the rejection is maintained.

7. The rejection of claims 19-25 and 27-29 under 35 U.S.C. 103(a) as being unpatentable over Wendel et al. (EPA 741,294, DE Appl. 19, 516,247), in view of

Dinarello (US Patent 4,434,237) and in further view of Boyse et al., (US Patent 5,192,553) is maintained for reasons already of record.

The rejection was on grounds it would have been obvious to have used the frozen whole blood samples and cryopreservation techniques of blood as taught by Dinarello and Boyse et al., (US Patent 5,192,553), in the method of determination as taught by Wendel et al., because Dinarello ~~teaches~~ frozen blood is protected against cellular injury while Boyse et al., teach frozen blood that does not lose its ability to function, thus both teach frozen storage techniques that would be advantageous in a method of determining blood reactions.

In response to applicant's arguments against the references individually, in that Dinarello does not teach the use of whole blood; while Boyse et al., (5,192,553) teach diagnostic methods and products, One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is the examiner's position that Wendel et al. (EPA 741,294, DE Appl. 19, 516,247), in view of Dinarello (US Patent 4,434,237) and further in view of Boyse et al., (US Patent 5,192,553) teach a method of determining the reaction of whole cryopreserved blood wherein the reaction of the blood is measured by the recited methods.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious to have used the frozen and cryopreservation techniques of blood as taught by Boyse et al., (US Patent 5,192,553), with the whole blood samples of Wendel et al., and the method of determining the reaction of blood as taught by Wendell et al., and Dinarello because Dinarello teaches frozen blood is protected against cellular injury and both Boyse et al., and Dinarello teach blood can be stored and this would provide an advantage in the method of determination as taught by Wendel et al.

***New Grounds for Rejection***  
***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 19-25 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims. Claim 19 is indefinite in the recitation of "adequate blood response." It is unclear how to define what is or is not an adequate blood response. It is unclear if only the release of cytokinins is an adequate blood response or if there are other adequate responses. Claim 25 recites measuring the "blood reaction." Neither the specification nor the claims teach a definition of blood reaction. Thus it is unclear

Art Unit: 1645

how to determine what reactions are or are not encompassed by the term blood reaction.

Clarification is required in order to overcome this rejection.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 

December 6, 2001

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
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